

**Notice of Allowability**

Application No.

10/577,334

Examiner

Alicia L. Fierro

Applicant(s)

GYORKOS ET AL.

Art Unit

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments filed 9/16/09.
2. ☒ The allowed claim(s) is/are 1,3-5,13,15 and 18.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- \* Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 11/19/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

/REI-TSANG SHIAO /  
Primary Examiner, Art Unit 1628

**DETAILED ACTION**

1. The amendments to the claims, filed on September 16, 2009, are acknowledged and have been entered.

**RESTRICTIONS/ELECTIONS**

2. The requirement for restriction and species election in the restriction requirement dated December 31, 2008 is hereby withdrawn.

**INFORMATION DISCLOSURE STATEMENT**

3. The information disclosure statement (IDS) submitted on November 19, 2007 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly the IDS document was considered and a signed copy of form 1449 has been enclosed herewith.

**EXAMINER'S AMENDMENT**

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bill Schmidt on November 20, 2009.

**In the Claims:**

**Please amend the claims as follows:**

Claim 1

Please INSERT a closed parenthesis ---)--- after the phrase

“wherein R<sup>5</sup> is a C<sub>1-4</sub>alkyl.”

Claims 13 and 15      INSERT the phrase ---wherein the disease to be treated is selected from affective disorder, depression, and anxiety--- after the phrase "for treating a disease wherein a CRF receptor is implicated."

Claim 18      Please INSERT the status identifier “currently amended” after the claim number.

Claims 14, 16 and 17      Please CANCEL claims 14, 16 and 17.

**Please amend the specification as follows:**

**Please amend the first sentence of the specification to read** "This application claims priority to U.S. Provision Application No. 60/516,164, filed October 31, 2003 and U.S. Provisional Application No. 60/560,518 filed April 8, 2004.

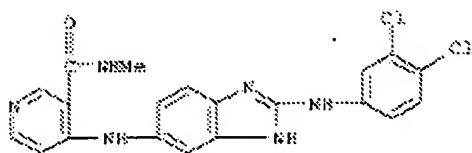
**REASONS FOR ALLOWANCE**

5.      The following is an examiner’s statement of reasons for allowance: The instantly claimed compounds are novel and non-obvious over the prior art because of the following structural limitation: **The R<sup>1</sup> and R<sup>5</sup> groups as recited in claim 1.** The closest prior art is Di Pietro et al., US Patent No 7,531,553, which has a priority date of March 21, 2003. This reference does not encompass the scope of the instant application, which includes the following novelties: the R<sup>1</sup>

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amino group must be disubstituted by an optionally substituted  $C_{1-4}$  alkyl, phenyl or pyridyl group and  $R^5$  must be  $C_{1-4}$  alkyl.

6. The '553 patent discloses the following compound as compound 60 in Table 5, column 114, which has a similar core to the instantly claimed compounds, but without the novelty identified above.



The compounds fits within the instantly claimed formula (I) with the exception of the  $R^5$  group, which is H rather than  $C_{1-4}$  alkyl and that the  $R^1$  group is a monosubstituted amino group rather than disubstituted which is not in the instantly claimed formula. Further, the  $W-R^1$  substituent is at the 6 position of the benzimidazole ring rather than the 7 position so the compounds are also positional isomers. The instant compounds have a utility as modulators of CRF receptors, while those of the '553 patent are disclosed as being useful kinase inhibitors. The instant claims do not encompass any compounds with  $R^1$  being only monosubstituted with the claimed substituents nor are there any compounds claimed where  $R^5$  is other than alkyl. The prior art reference does not contain the identical or obvious substituents at the aforementioned positions. A person of ordinary skill in the art would not have expected that making these structural modifications would retain identical activity as disclosed in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Conclusion*

7. Claims 1, 3-5, 13, 15 and 18 (renumbered 1-7) are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday through Thursday, 6:00 – 4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1626

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